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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,584

06/27/2003

Yu Liu

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EXAMINER

VATHYAM, SUREKHA

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,584

Applicant(s)

LIU ET AL.

Examiner

Surekha Vathyam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/20/03, 01/09/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 10/20/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein with regards to non-patent literature publication has not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19 – 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Independent claim 19 and dependent claims 20 – 36 thereof recite the limitation "said analytes" in line 9 of the claim 19. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 9, 11 – 13, 16 – 27, 29 – 31 and 34 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guttman et al. (US 5,370,777).

Regarding claim 1, Guttman ('777) discloses an aqueous gel medium (column 6, lines 44 – 51) for facilitating the electrophoretic separation of analytes present in a sample (column 5, line 36 – 40), said medium comprising: a non-crosslinked (column 9, lines 22 – 37) hydrophilic polymer (column 8, lines 45 – 54);

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tris(hydroxymethyl)aminomethane – borate buffer (column 5, lines 63 – 67); sodium dodecyl sulfate (column 9, lines 53 – 55); and an organic additive (column 9, lines 38 – 45); and wherein said aqueous gel medium facilitates the electrophoretic separation of said analytes by comprising a molecular sieve (column 9, lines 14 – 21).

Guttman ('777) further discloses that the pH of the tris(hydroxymethyl)aminomethane – borate buffer is “preferably between about 8.0 and about 8.5, and most preferably about 8.3” (column 13, lines 12 – 16). The difference between instant claim 1 and Guttman ('777) is that claim 1 requires a pH above 8.0 and below 8.3, while Guttman ('777) does not disclose a specific point within this range but instead discloses ranges encompassing the claimed range (such as about 8.0 to about 8.5) as well as the overlapping range “about 8.3”. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). “[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness.” *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Regarding claim 2, Guttman ('777) discloses the aqueous gel medium wherein said gel medium additionally contains one or more reagent(s) that function to help keep protein analytes in a reduced form (column 18, lines 22 – 42).

Regarding claim 3, Guttman ('777) discloses the aqueous gel medium wherein said one or more reagent(s) include a reducing reagent (column 18, lines 22 – 42).

Regarding claim 4, Guttman ('777) discloses the aqueous gel medium wherein said reducing reagent is selected from the group consisting of 2-mercaptoethanol, dithiothreitol (DTT), dithioerythreitol (DTE), and tris(2-carboxyethyl)phosphine (column 18, lines 22 – 42).

Regarding claim 5, Guttman ('777) discloses the aqueous gel medium wherein said reducing reagent is dithiothreitol (DTT) (column 18, lines 22 – 42).

Regarding claim 6, Guttman ('777) discloses the aqueous gel medium wherein said one or more reagent(s) include a metal ion chelator (column 19, lines 4 – 5).

Regarding claim 7, Guttman ('777) discloses the aqueous gel medium wherein said reducing reagent is ethylenediaminetetraacetic acid (EDTA) (column 19, lines 4 – 5)..

Regarding claim 8, Guttman ('777) discloses the aqueous gel medium wherein said non-crosslinked hydrophilic polymer is selected from the group consisting of: dextran, polyacrylamide, cellulose derivatives and polyethylene oxide (column 8, lines 50 – 54).

Regarding claim 9, Guttman ('777) discloses the aqueous gel medium wherein said non-crosslinked hydrophilic polymer is dextran (column 8, lines 50 – 54).

Regarding claim 11, Guttman ('777) discloses the aqueous gel medium wherein said organic additive is an alcohol (column 9, lines 38 – 45).

Regarding claim 12, Guttman ('777) discloses the aqueous gel medium wherein said alcohol is present at a concentration of from about 0.1% to about 30% (V/V) (column 9, lines 23 – 30).

Regarding claim 13, Guttman ('777) discloses the aqueous gel medium wherein said alcohol is selected from the group consisting of: methanol, ethanol, ethylene glycol and glycerol (column 9, lines 38 – 45).

Regarding claim 16, Guttman ('777) discloses the aqueous gel medium wherein said Tris-borate buffer is present at a concentration of from about 0.1 M to about 1.0M (column 10, lines 51 – 54).

Regarding claim 17, Guttman ('777) discloses the aqueous gel medium wherein the pH is "preferably between about 8.0 and about 8.5, and most preferably about 8.3" (column 13, lines 12 – 16). The difference between instant claim 17 and Guttman ('777) is that claim 17 requires a pH of 8.1 ± 0.1 , while Guttman ('777) does not disclose a specific point within this range but instead discloses ranges encompassing the claimed range (such as about 8.0 to about 8.5). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Regarding claim 18, Guttman ('777) discloses the aqueous gel medium wherein said analytes include analytes selected from the group consisting of: proteins, polypeptides, peptides and nucleic acid molecules (column 10, lines 1 – 20).

Regarding claim 18, Guttman ('777) discloses a capillary electrophoresis system (column 6, lines 44 – 51) comprising a capillary tube (column 6, lines 52 – 57) containing an aqueous gel medium (column 6, lines 44 – 51), said medium comprising: a non-crosslinked (column 9, lines 22 – 37) hydrophilic polymer (column 8, lines 45 – 54); tris(hydroxymethyl)aminomethane – borate buffer (column 5, lines 63 – 67); sodium dodecyl sulfate (column 9, lines 53 – 55); and an organic additive (column 9, lines 38 – 45); and wherein said aqueous gel medium facilitates the electrophoretic separation of said analytes (column 5, line 36 – 40) by comprising a molecular sieve (column 9, lines 14 – 21).

Guttman ('777) further discloses that the pH of the tris(hydroxymethyl)aminomethane – borate buffer is “preferably between about 8.0 and about 8.5, and most preferably about 8.3” (column 13, lines 12 – 16). The difference between instant claim 19 and Guttman ('777) is that claim 19 requires a pH above 8.0 and below 8.3, while Guttman ('777) does not disclose a specific point within this range but instead discloses ranges encompassing the claimed range (such as about 8.0 to about 8.5) as well as the overlapping range “about 8.3”. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). “[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness.” *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Regarding claim 20, Guttman ('777) discloses the capillary electrophoresis system wherein said gel medium additionally contains one or more reagent(s) that function to help keep protein analytes in a reduced form (column 18, lines 22 – 42).

Regarding claim 21, Guttman ('777) discloses the capillary electrophoresis system wherein said one or more reagent(s) include a reducing reagent (column 18, lines 22 – 42).

Regarding claim 22, Guttman ('777) discloses the capillary electrophoresis system wherein said reducing reagent is selected from the group consisting of 2-mercaptoethanol, dithiothreitol (DTT), dithioerythritol (DTE), and tris(2-carboxyethyl)phosphine (column 18, lines 22 – 42).

Regarding claim 23, Guttman ('777) discloses the capillary electrophoresis system wherein said reducing reagent is dithiothreitol (DTT) (column 18, lines 22 – 42).

Regarding claim 24, Guttman ('777) discloses the capillary electrophoresis system wherein said one or more reagent(s) include a metal ion chelator (column 19, lines 4 – 5).

Regarding claim 25, Guttman ('777) discloses the capillary electrophoresis system wherein said reducing reagent is ethylenediaminetetraacetic acid (EDTA) (column 19, lines 4 – 5).

Regarding claim 26, Guttman ('777) discloses the capillary electrophoresis system wherein said non-crosslinked hydrophilic polymer is selected from the group consisting of: dextran, polyacrylamide, cellulose derivatives and polyethylene oxide (column 8, lines 50 – 54).

Regarding claim 27, Guttman ('777) discloses the capillary electrophoresis system wherein said non-crosslinked hydrophilic polymer is dextran (column 8, lines 50 – 54).

Regarding claim 29, Guttman ('777) discloses the capillary electrophoresis system wherein said organic additive is an alcohol (column 9, lines 38 – 45).

Regarding claim 30, Guttman ('777) discloses the capillary electrophoresis system wherein said alcohol is present at a concentration of from about 0.1% to about 30% (V/V) (column 9, lines 23 – 30).

Regarding claim 31, Guttman ('777) discloses the capillary electrophoresis system wherein said alcohol is selected from the group consisting of: methanol, ethanol, ethylene glycol and glycerol (column 9, lines 38 – 45).

Regarding claim 34, Guttman ('777) discloses the capillary electrophoresis system wherein said Tris-borate buffer is present at a concentration of from about 0.1 M to about 1.0M (column 10, lines 51 – 54).

Regarding claim 35, Guttman ('777) discloses the capillary electrophoresis system wherein the pH is "preferably between about 8.0 and about 8.5, and most preferably about 8.3" (column 13, lines 12 – 16). The difference between instant claim 35 and Guttman ('777) is that claim 35 requires a pH of 8.1 ± 0.1 , while Guttman ('777) does not disclose a specific point within this range but instead discloses ranges encompassing the claimed range (such as about 8.0 to about 8.5). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

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"[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Regarding claim 36, Guttman ('777) discloses the capillary electrophoresis system wherein said analytes include analytes selected from the group consisting of: proteins, polypeptides, peptides, polysaccharides, and nucleic acid molecules (column 10, lines 1 – 20).

9. Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guttman et al. (US 5,370,777) in view of King (US 3,622,661).

Guttman ('777) discloses the aqueous gel medium as discussed with regards to claim 8 above.

Regarding claim 10, Guttman ('777) discloses the aqueous gel medium wherein said dextran has a molecular weight of 2,000 kilodaltons (column 5, lines 63 – 67) but does not explicitly disclose the linkages therein. The King ('661) reference is cited as evidence that commercially available dextran possesses a non-cross-linked structure composed of approximately 95% alpha-D-(1-6) linkages (column 1, lines 41 – 43).

Guttman ('777) discloses the capillary electrophoresis system as discussed with regards to claim 27 above.

Regarding claim 28, Guttman ('777) discloses the capillary electrophoresis system wherein said dextran has a molecular weight of 2,000 kilodaltons (column 5,

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lines 63 – 67) but does not explicitly disclose the linkages therein. The King ('661) reference is cited as evidence that commercially available dextran possesses a non-cross-linked structure composed of approximately 95% alpha-D-(1-6) linkages (column 1, lines 41 – 43).

10. Claims 14 – 15 and 32 – 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guttman et al. (US 5,370,777) in view of Guttman (US 5,213,669).

Guttman ('777) discloses the aqueous gel medium as discussed with regards to claim 13 above.

Regarding claim 14, Guttman ('777) does not explicitly disclose the alcohol is glycerol.

Guttman ('669) teaches an aqueous gel medium wherein the alcohol is glycerol (column 5, lines 7 – 8).

It would have been obvious to one of ordinary skill in the art to have modified the aqueous gel medium of Guttman ('777) to include glycerol as taught by Guttman ('669) because as explained by Guttman ('669), the "polyol" (glycerol and ethylene glycol being representative examples), help to coat the inner walls of capillaries that they occupy (column 5, lines 3 – 7).

Regarding claim 15, Guttman ('669) teaches an aqueous gel medium wherein glycerol is present at a concentration of from about 0.1% to about 30% (V/V) (column 4, line 67 – column 5, line 3).

Guttman ('777) discloses the capillary electrophoresis system as discussed with regards to claim 31 above.

Regarding claim 32, Guttman ('777) does not explicitly disclose the alcohol is glycerol.

Guttman ('669) teaches a capillary electrophoresis system wherein the alcohol is glycerol (column 5, lines 7 – 8).

It would have been obvious to one of ordinary skill in the art to have modified the capillary electrophoresis system of Guttman ('777) to include glycerol as taught by Guttman ('669) because as explained by Guttman ('669), the "polyol" (glycerol and ethylene glycol being representative examples), help to coat the inner walls of capillaries that they occupy (column 5, lines 3 – 7).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tan et al. (US 6,787,016) discloses non-crosslinked hydrophilic polymer with SDS, tris-borate buffer for use in molecular sieving in capillary electrophoresis separation medium.

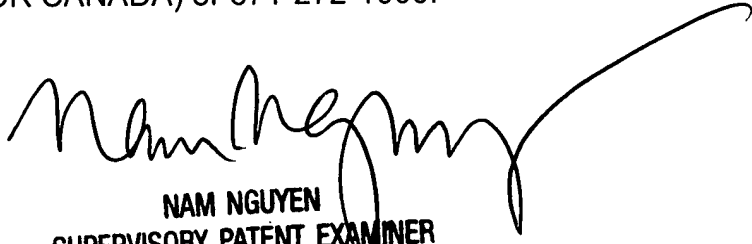
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SV
December 8, 2006


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SUPERVISORY PATENT EXAMINER
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